Drug Utilization Review Board Meeting Minutes, Open Session October 12, 2011		
Drug Utilization Review Board Meeting Minutes, Open Session HP Enterprise Services / Forbes Field Capital / Cedar Crest Room Topeka, KS	**Members Present:** Michael Burke, M.D., Ph.D., Chair Judy McDaniel Dowd, PA-C Daniel Sutherland, R.Ph. Roger Unruh, D.O. Kevin Waite, Pharm.D. **Member Absent** Dennis Grauer, Ph.D. John Kollhoff, Pharm.D. **DHCF Staff Present:** Kelley Melton, Pharm.D. Shea Robinson Shelly Liby Margaret Smith, M.D., M.P.H., M.H.S.A. **HP Enterprise Services Staff Present:** Deb Quintanilla, R.N. Lisa Todd, R.Ph. Karen Kluczykowski, RPh Nicole Churchwell, Pharm.D. **HID Staff Present** Nicole Churchwell, Pharm.D. **ACS Staff Present** Bethany Noble, C.Ph.T Larry Dent, Pharm.D.	**Representatives:** Laura Nichols, GSK Phil King, Pfizer Teresa Blair, Amgen Carol Curtis, AstaZeneca Dave Sproat, Bristol-Myers Squibb Nick Boyer, AstraZeneca Julie McDavitt, Boehringer-Ingelheim Ann Hartry, Endo Kathleen Karnik, Janssen Mark Weizs, Otsuka Matthew Stafford, Merck Joe Summers, Takeda Berend Koops, Merck Brian Rose, Savient
TOPIC	**DISCUSSION**	**DECISION AND/OR ACTION**
I. Call to Order	Dr. Burke, Chair called the meeting to order at 10:04 a.m.	
II. Announcements	Nicole Churchwell advised the attendees that the parking spaces in the front of the building (east side) are available for the Board members and that there is additional parking on the west side of the HP office for visitors. Public comments are limited to five minutes & you will need to fill out a public disclosure form & return it.	
III. Old Business A. Review and Approval of 6/15/11 Meeting Minutes	No changes made.	Judy McDaniel Dowd moved to approve the minutes. Dr. Waite seconded and it carried with a unanimous vote.
IV. New Business A. Short-Acting Transmucosal Fentanyl Products (Actiq®,	<u>Background</u> The short-acting transmucosal fentanyl products have required prior authorization since 2006. This group of products was last reviewed in April 2011 when Abstral was added to	Dr. Wait moved to accept the PA as presented.

Fentora®, Onsolis®, Abstral® and Lazanda®) i. Revises Clinical PA Criteria ii. *Public Comment iii. Board Discussion/Action	the current criteria; since that time a new agent has been approved, Lazanda nasal spray. It is recommended that Lazanda be added to the current criteria and that the criteria be revised to reflect changes in the package inserts for several products regarding new REMS programs. No Public Comments. <u>Board Discussion</u> Dr. Dent stated the current limit on short-acting transmucosal fentanyl products is 4 units per day for Actiq, Fentanyl, Onsolis, & Abstral. For Lazanda the proposed dosing limit will be 8 sprays a day or 1 bottle.	Dr. Sutherland seconded the motion. The motion passed unanimously.
B. High-Dose Short Acting Opioids i. Revised Clinical PA Criteria ii. *Public Comment iii. Board Discussion	<u>Background</u> The high-dose short-acting opioids criteria was last reviewed in April 2011 when Abstral was added to the criteria; since that time a new agent has been approved, Lazanda nasal spray. It is recommended that Lazanda be added to the current criteria. Dr. Churchwell added that this is for doses above morphine equivalents of 200 mg per day. For patients that are terminally ill, diagnosed with cancer, or meets the four criteria, the criteria stays the same, Lazanda is just being added. The Fentanyl products should be included in this PA even though they don't have a direct morphine equivalent dose. Dr. Burke mentioned we have discussed this topic for years. No Public Comments <u>Board Discussion</u> Dr. Burke clarified that we are adding Lazanda to the morphine equivalence table for restriction or PA requirement greater than 200 mg per day.	Dr. Sutherland made a motion to accept the addition of Lazanda to the high dose PA Dr. Dowd seconded the motion
C. Nuedexta® (dextromethorphan/ quinidine) i. Revised Clinical PA Criteria ii. *Public Comment iii. Board Discussion	<u>Background</u> Nuedexta is a combination product for the treatment of pseudobulbar affect (PBA). Dextromethorphan stimulates sigma-1 receptors and inhibits NMDA receptors, and quinidine inhibits dextromethorphan metabolism increasing bioavailability. Studies to support the effectiveness of Nuedexta were conducted in patients with underlying amyotrophic lateral sclerosis (ALS) and multiple sclerosis (MS); however, effectiveness can be extrapolated to PBA that occurs in other neurologic conditions. It is recommended that the current criteria be revised to remove the "secondary to ALS or MS" portion of the criteria. No Public Comments <u>Board Discussion</u> Dr. Burke stated that we are broadening the indications and adding the safety criteria.	Dr. Waite made a motion to accept the new updates PA for Nuedexta. Dr. Dowd seconded the motion. The motion passed unanimously.

	Dr. Dowd asked about the sentence, 'the patient does not have a history of complete AV Block without a pacemaker'. Does that mean if they have AV Block with a pacemaker, it is not excluded? Dr. Smith stated that the pacemaker would take over the function so it wouldn't interfere. Dr. Burke suggested this is where the subscriber needs to step up and take responsibility for knowing contraindications. Sometimes we want to include them on the PA which is okay. Dr. Dent answered the way criteria will be written is if a patient has a history of AV Block and has not been on a pacemaker, they will be excluded from receiving this drug. If they have a pacemaker they will not be excluded. Dr. Dowd asked if it would be clearer to say 'the patient has no history of congenital long QT syndrome or heart failure nor history of AV Block prior to pacemaker'. Dr. Dent replied there is probably a better way to word the sentence. Overall the point is those patients will be excluded because of safety issues. If patients are identified as having AV Block, they will be excluded unless they have a pacemaker. Dr. Burke noted that the package insert also calls attention to patients at high risk of complete AV Block so you have to draw the line somewhere in terms of overseeing it. Debra Quintanilla asked if ACS would look back in the patient's history. Bethany Noble responded that the criteria would look at the history and if it was denied at that point, the call would go to the call center. Dr. Melton added that ACS could set it up so that it hits a question, does this person have AV Block? If the answer is yes, it hits another question. Do they have a pacemaker, yes or no? Bethany Noble confirmed that was an option for setting up the flowchart. Dr. Burke wondered if other third party payors do this or if they delegate the responsibility for prescribing to the prescriber. An example he provided in the situation when somebody might have Long QT syndrome but their doctor feels their functions are so low, they can't get out of their room. They feel it's a reasonable thing to try and monitor. They could make that a case. Dr. Sutherland stated he's curious because historically we try to stick to what the package inserts says don't stray with language that creates exceptions. Dr. Burke answered we don't always put in the contraindications. Dr. Sutherland answered when we do; it's typically right down the line as the package insert. He questioned why not state it exactly the way it is on the insert so it's absolutely clear and consistent. Dr. Burke answered this says complete AV Block without implanted pacemaker. Dr. Sutherland answered that was pretty close.	
D. Long-Acting Beta-Agonists (Brovana® (arformoterol), Foradil® and Perforomist® (formoterol),	<u>Background</u> In March 2009 the DUR Board approved prior authorization criteria for Foradil and Serevent Diskus due to the FDA warning regarding the risk of asthma related deaths associated with the utilization of long-acting beta-agonists alone. Other long-acting beta-	Dr. Unruh made a motion to accept the new PA proposal. Dr. Sutherland seconded the

Arcapta® (indacaterol) and Serevent® Diskus salmeterol)) i. Revised Clinical PA Criteria ii. *Public Comment iii. Board Discussion	agonists have entered the market since this time, and it is proposed that these agents be added to this prior authorization criteria. No Public Comment <u>Board Discussion</u> Dr. Burke stated that this is straight forward, adding a couple of new agents.	motion. The motion passed unanimously.
E. Xarelto (rivaroxaban) i. Day Supply Limit, Override PA criteria, Diagnosis Restrictions ii. *Public Comment iii. Board Discussion	<u>Background</u> Xarelto is an anticoagulant indicated for the prophylaxis of deep vein thrombosis, which may lead to pulmonary embolism (PE) in patients undergoing knee or hip replacement surgery. For patients undergoing hip replacement surgery, treatment duration of 35 days is recommended and for patients undergoing knee replacement surgery, treatment duration of 12 days is recommended. It is proposed that a limit be placed on Xarelto for a total of 35 days per year. Additional courses of therapy will require prior authorization. <u>Public Comment</u> Kathleen Karnik, Jansen Pharmaceuticals, stated that the company agrees with the PA criteria. Since it's a new product, she wanted to make herself available to the committee to answer any questions. Dr. Burke asked what if they need more than the proposed limit. Kathleen Karnik answered, from an extension perspective, if a beneficiary had a knee replacement then threw out a hip, another procedure would be necessary. If this criteria would allow that PA to go through, that would be acceptable. The other issue would be if a patient was on a medication that would require the patient to use double the dose. Dr. Churchwell asked if the day supply should be looked at and not the dose per day. Dr. Sutherland stated that that scenario wouldn't mean they wouldn't have to take it any longer than the standard course. Kathleen Karnik stated that was correct. Dr. Burke noticed that 3A4 is involved and asked if Ms Karnik could provide information about the drug interaction. She responded one third of the drug is metabolized and then it's excreted. Only those products that have a very strong 3A4 or PGP inhibition actually affect Xarelto. The FDA put on another requirement for an inducer and if it was a strong inducer then the drug will need to be used in double dosages. Dr. Burke mentioned the biggest concern would be acute interactions with 3A4 inhibitors that would increase the Xarelto. Ms. Karnik responded that is correct but only if it's a strong 3A4 inhibitor. <u>Board Discussion</u> There was no board discussion.	Dr. Dowd made a motion to accept the PA criteria for Xarelto. Dr. Sutherland seconded the motion. The motion passed unanimously.
F. Flexeril, Fexmid and Amrix (cyclobenzaprine) i. Day Supply Limit, Dose	<u>Background</u> Cyclobenzaprine is a skeletal muscle relaxant indicated as an adjunct to rest and physical therapy for relief of muscle spasms associated with acute, painful musculoskeletal	Dr. Dowd made a motion to table the cyclobenzaprine action.

Per Day Limit, Override Criteria ii. *Public Comment iii. Board Discussion	conditions. Cyclobenzaprine should only be used for short periods of (up to two or three weeks); the recommended maximum dose is 30 mg per day. The DEA recently issued a warning stating that cyclobenzaprine may be subject to intentional misuse and abuse. A review of Kansas Medical Assistance Programs utilization data shows beneficiaries using cyclobenzaprine at higher doses and durations longer than recommended by the package insert. The proposed limit is 30 mg per day for 21 days. Additional courses of therapy will require prior authorization. These limits are similar to what was approved for Soma in October 2010. No Public Comment <u>Board Discussion</u> Dr. Burke stated the number of beneficiaries that are getting more than the 30 mgs a day is interesting. He indicated that he spoke to some clinicians in the Wichita Pain Management group. They felt there are cases where longer duration therapy is appropriate. With the new PA, they can, after they get the initial 21 days. Dr. Churchwell added then the criteria would be that they would have a new muscle injury. Dr. Waite added its 60% of the beneficiaries that are above the limit. Dr. Burke asked how someone can get an extension for duration. Dr. Smith replied that the doctor will have to call for an appeal. Dr. Churchwell noted, there are two separate things to approve. The maximum dose per day of 30 mg is one issue and the 21 day supply limit is another issue. Dr. Burke stated he consulted with a couple of doctors. They both were less concerned about the 30 mg a day, but felt there are case where the patients received benefits from longer therapy. These are people who have other than acute orthopedic injuries. Dr. Dowd asked if they need to do an appeal, that would be for one fill of 21 days and they would need to do it every 21 days for chronic use. Dr. Smith answered unless we approved it for a longer period. Dr. Smith said when she was in practice she used it for longer than 21 days. Dr. Burke asked if there was a way to add something for the chronic pain patient that is not a new muscle injury. Dr. Churchwell responded that criteria could be added but the physician must provide documentation of the necessity of use. Dr. Sutherland stated that would be outside the package insert indications from the manufacturer, which the board typically doesn't do. Dr. Waite said he thinks it's going to cause dissatisfaction among providers and those of you who have to deal with the downstream flow of it. Dr. Sutherland stated the	The motion was seconded by the Dr. Unruh. The motion passed unanimously.

	manufacturer doesn't suggest use for more than 21 days and that's our standard for health care. Dr. Dowd asked if the prior authorization stated 'manage by pain management'? Dr. Churchwell replied that it's just the new muscle injury that's on the criteria now. We didn't require pain management because it's not available to the rural areas. Dr. Burke asked if there is away to compromise. Dr. Churchwell stated you can approve them separately. Dr. Burke asked about approving it and then revisiting it in six months to see if there is backlash. If we approve it, how long will it take to implement it? Dr. Melton answered if it's just day and quantity supply, prior authorization approval isn't necessary by through the rules and regulations process. These would be restrictions placed in the claims processing system and can implemented quickly. Dr. Burke suggested we table this discussion. Future review will look for extended uses, above the maximum recommended dosages, and how long patients are on it. Dr. Burke mentioned we will see this again next year.	
G. Supprelin LA (histrelin acetate) i. New Clinical PA Criteria ii. *Public Comment iii. Board Discussion	<u>Background</u> Supprelin LA is a gonadotropin-releasing hormone (GnRH) agonist indicated for the treatment of children with central precocious puberty (CPP). Children with CPP (neurogenic or idiopathic) have an early onset of secondary sexual characteristics (earlier than 8 years of age in females and 9 years of age in males). They also show a significantly advanced bone age that can result in diminished adult height attainment. Supprelin LA is similar to Lupron, which had prior authorization criteria approved in April 2011 due to the off-label utilization in autism and short stature. Prior authorization criteria are being proposed for Supprelin LA to prevent patients from switching from Lupron to Supprelin LA once the prior authorization is implemented for Lupron. <u>Public Comment</u> Ann Hartry, Endo, says this PA makes sense, the company will support it but requests a small administrative change. The payment for product and implementation are bundled in Kansas. Most states have found it works better to split out the payment to the surgeon doing the implant from payment for the product because they are different physicians. That's what standing in the way of patients getting this product in this state. Other states have implemented this. Dr. Smith replied that a policy change would need to be requested but it can be done. She requested the procedure codes. Ms. Hartry indicated the codes are 11981, 11982, and 11983. <u>Board Discussion</u> There was no board discussion.	Dr. Waite made a motion to accept the PA. Dr. Unruh seconded the motion. The motion passed unanimously.
H. Krystexxa (pegloticase) i. New Clinical PA	<u>Background</u> Krystexxa is a PEGylated uric acid specific enzyme indicated for the treatment of chronic	Dr. Dowd made a motion to accept the PA criteria.

Criteria ii. *Public Comments iii. Board Discussion	gout in adult patients refractory to conventional therapy. Currently there are no off-label uses in DrugDex for Krystexxa but there have been reports that similar medications are used for preventing high uric acid due to cancer treatments and preventing recurring kidney stones in patients with high uric acid levels and Krystexxa could possibly be used off-label for this. Prior authorization criteria are being proposed to ensure appropriate use in adult patients with chronic gout who are refractory to conventional therapy and to prevent off-label utilization for unapproved indications. <u>Public Comment</u> Brian Rose, Savient Pharmaceuticals, stated that he would like to explain the patient population for Chronic Gout. Out of the 8 million gout sufferers, 128,000 folks are appropriate for Krystexxa. Dr. Burke stated one of the purposes was to avoid off label use. Chemotherapy patients and those with kidney stones have been discussed and the committee doesn't want to withhold something from those populations that might be helpful. He asked Mr. Rose if the company was studying those disease states. Mr. Rose responded that they are not and the drug is for chronic gout only. There are a couple of safety guidelines to stick to. Uric acid has to be monitored prior to every infusion because individuals that are considered non-responders are more prone to have infusion reactions. The only contraindication with product or individuals who are G6PD deficient and they recommend screening prior to with every patient. <u>Board Discussion</u> Dr. Burke asked if we had the safety concerns in the PA or if they should be included. Dr. Churchwell replied that they were not be could be. The step to indicate uric acid needs to be monitored before each infusion could be added. They could request to see if the level is above 6 or not. Dr. Dowd if the committee wanted to add the G6 PD. Dr. Churchwell responded that it could be added as well. Dr. Burke asked who would be ordering and doing the infusions every two weeks. Dr. Smith said a specialist would do that. Dr. Burke asked if a specialist has some responsibility for doing the uric acid levels. Dr. Sutherland asked what has historically been done as far as the black box warning. Dr. Churchwell replied that a special note is included on the criteria but it's not included as part of the criteria itself. Dr. Waite said that makes sense and felt it should be in front of it. Dr. Burke stated we could add it under the note section. Dr. Melton asked Dr. Smith if we pay for genotyping. Dr. Smith said yes, in some instances	Dr. Sutherland seconded the motion. The motion passed unanimously.

	but didn't know if it was covered for G6 PD deficiencies. Dr. Burke asked that the black box warning and some safety notes be added to the criteria.	
	The DUR Committee meeting was adjourned at 10:54 am. The DUR and PERC Committee reconvened at 11:02 am.	
I. Program Assessment and Intervention Topic Selection i. Program Assessment, Intervention Topic Selection ii. *Public Comment iii. Board Discussion	<u>Background</u> Each year the DUR Board is presented with the program assessment, which includes analysis of utilization trends from the previous state fiscal year. Following the program assessment, the DUR Board will be asked to choose the remaining intervention topics; each year five topics are chosen for review. In June 2011 the DUR Board chose the first two topics: cardiometabolic side effects of antipsychotic agents and drug interactions in patients with seizure disorders. Dr Burke called the meeting to order at 11:02 am. He welcomed the PERC Committee members. The PERC members introduced themselves: Salley Page-Goertz, Jeff Pierce, & Dr. Brandon Kennedy Dr. Nicole Churchwell introduced herself and stated that she is going to talk about the program assessment for fiscal year 2011. It includes dates of service from July 1, 2010 thru June 30, 2011. We are going to talk about other years too. We are going to talk about the yearly totals as well as eligibility totals. We are going to look at the trends. We are going to look at the different levels of drug classification reporting. There are three classes: therapeutic, generic, and specific drug level. We will look at trends within those groups. I'm also going to give a brief overview of the DUR program and newsletters. At the end the board will have an opportunity to select intervention topics. They selected two topics in June, so today they will select the final three for state fiscal year 2012. The Yearly Totals – In SFY 2009, the program spent $175 million on just over 2 million prescriptions. In 2010, pharmacy spend dropped to $160 million even though the number of claims increased by approximately 80,000. In SFY 2011, the costs came back up to $172 million, with about 2.1 million prescriptions filled. During this same time period both members and users of pharmacy services have continued to increase. However, only about 43% of the total members over the past 3 years have received pharmacy services. Even though the total prescription expenditures increased between SFY 2010 to SFY 2011 they were still less than the expenditures in SFY 2009. This can be attributed to : Continued management of State Maximum Allowable Cost (SMAC) -SMAC is a limit on what KDHE-DHCF will pay for a drug when there are multiple manufacturers available. -During SFY 2011 there were SMAC price updates over 2,100 NDCs and nearly 50% of claims were paid using SMAC pricing.	Dr. Dowd made a motion to accept the final intervention topics. Mr. Sutherland seconded the motion. The motion passed unanimously.

	Continued savings from TPL (Third Party Liability) Cost Avoidance -TPL Cost Avoidance denies claims for beneficiaries who have primary insurance if payment or denial from the primary insurance is not indicated on the claim. -TPL Cost Avoidance was implemented in January 2009. Eligibility Totals – The total number of beneficiaries eligible for services for all Kansas Medical Assistance Programs has steadily increased from just over 307,000 in July 2008 to nearly 375,000 in June 2011, an increase of nearly 67,000. The number of FFS members peaked from July to January, but it has leveled back off. The number of MCO eligible beneficiaries has increased over the past two fiscal years. Drug Classification Reporting There are three levels of drug classification reporting. Therapeutic Class - Proton Pump Inhibitors (all agents). Generic Ingredient Level – Lansoprazole (includes all generic lansoprazole and brand Prevacid products together) Drug Level - Lansoprazole generic products and Prevacid branded products reported separately. Data is reported at each drug classification level in two ways to help determine where there is a potential for clinically significant interventions or cost savings: Total Claims – identifies the most commonly prescribed medications Total Claims Cost – identifies which classes or drugs constitute the largest expenditures The top therapeutic classes by total number of claims remained nearly unchanged from SFY2010 to SFY2011. The ranking of the top 10 classes remained unchanged. The main difference was the addition of the miscellaneous central nervous system (CNS) agents to the top therapeutic classes by claims, which pushed biguanides out of the top 25. The miscellaneous CNS agents had the most significant change in total claims, from 18,126 in SFY2010 to 30, 989 in SFY2011. Many agents included in the miscellaneous CNS class are considered mental health medications; this class includes Strattera and Intuniv. Intuniv, extended-release guanfacine, has an average cost per claim in SFY2011 of $141. The central alpha agonists class, which includes Tenex (generic guanfacine) had the most significant decrease in total claims from SFY2010 to SFY 2011. In terms of total claims cost, the most significant percent change was in the miscellaneous CNS Agents class. Total claims cost increased nearly $2 million from about $2.7 million in SFY2010 to over $4.6 million in SFY2011. The most significant decrease in total claims	

	cost was seen in the proton pump inhibitors. Total claims cost went from $5.1 million in SFY2010 to $3.6 million in SFY2011, likely due to the availability of generic products such as lansoprazole. Looking at the trend over the past two years, for the miscellaneous CNS agents, an increase has been seen in both total claims and total claims cost. This increase is mainly due to the release of Intuniv, which became available in October of 2009. While utilization of proton pump inhibitors increased, the total claims cost decreased significantly. The average cost per claim went from over $130 from the first quarter of SFY2010 to less than $65 in the last quarter of SFY2011. Generic lansoprazole became available in the second quarter of SFY2010. Next, information will be reviewed at the generic ingredient level. Lansoprazole and Prevacid products will be reported together, as will Risperdal and Risperdal Consta. The generic ingredient with the most significant increase in total claims from SFY2010 to SFY2011 is guanfacine, which includes both Intuniv and generic guanfacine. Total claims increased from just over 12,000 in SFY2010 to over 24,000 in SFY2011, most likely due to the release of Intuniv. In looking at the most significant change in total claims cost at an ingredient level, guanfacine again showed the largest change. After guanfacine, paliperidone (the active metabolite of risperidone) showed the next highest increase. Paliperidone is only available as the branded product Invega. Total claims cost increased from around $2.6 million in 2010 to $4.7 million in 2011. While paliperidone costs were increasing, the total claims cost of risperidone was decreasing from nearly $4 million in SFY2010 to just over $3 million in SFY2011. Most risperidone products are now available generically. In reviewing trends for individual drugs, guanfacine utilization shows a huge increase in the second quarter of FY2010, when Intuniv entered the market. In the first quarter of SFY2010, the average cost per claim of generic guanfacine was around $9, but by the end of SFY2011, this had increased to nearly $120 per claim. Paliperidone has been available since 2007, and has shown a steady increase in claims since then. From SFY2007 to SFY2011, the total claims increased by 22%, while the total claims cost increase by 104%. With risperidone, however, total claims increased over the same time period, while total claims cost decreased. Now, in looking at claims on the specific drug level, lansoprazole generics and Prevacid brand are looked at separately. From SFY2010 to SFY2011, the most significant percent change in total claims was the increase in total claims for Intuniv (an increase of 5K to 18K in this time period).	

In terms of percent change of total claims cost, Intuniv again showed the largest increase. Others that also showed a large increase included Invega Sustenna, while Risperdal Consta showed a decrease.

Drugs of interest were also compared in terms of total claims and total claims cost. Comparisons were detailed for Invega Sustenna versus Risperdal Consta, as well as for Prevacid versus lansoprazole, which is a comparison that is especially appropriate for detailing the effects of a drug going generic, and Intuniv versus guanfacine.

In conclusion, over the past 3 years, total claims have increased; while total claims cost has fluctuated due to different factors. Several of the top therapeutic classes have been and continue to be mental health drug classes. Also, the availability of generic drugs significantly decreases the total claims cost.

Included for the board members are the DUR Newsletters from the past year, which had a variety of articles including ADHD medication holidays, safe prescribing of opioids, the Kansas vaccination schedule, and appropriate antibiotic utilization.

Dr. Churchwell also reported to the board that for the RetroDUR Academic Detailing program, over 60 prescribers receive Academic Detailing visits last June, with a focus on prescribers who received multiple DUR Intervention letters. She also reported on feedback from providers, including the usefulness of RetroDUR letters, the K-TRACs program, and awareness of prescribing from other physicians.

Each year, the DUR Board selects five intervention topics. In June 2011, board members chose the first two topics: cardiometabolic side effects of antipsychotic agents and drug interactions in patients with seizure disorders. The DUR Board is tasked with selecting the topics but welcomed comments and input from PERC. Dr. Churchwell presented the intervention letter process:

1) Claims data is sent to HID and loaded into the data mining tool, RxExplorer
2) Run the claims against the clinical criteria to identify and generate alert messages
3) An Initial Criteria Exception Report (ICER) is generated and reviewed to determine possible topics for review
4) DUR Board selects topics
5) A new, updated ICER is created for topics and beneficiary profiles are reviewed for appropriate lettering
6) Provider letters are generated which include the patient prescriptions, diagnoses and provider histories. Also included is an alert message and provider survey.

The topics presented for discussion were: appropriate migraine/headache therapy, NSAIDs and cardiovascular disease, therapeutic duplication, non-adherence to anti-hypertension

	regimen, polypsychopharmacy, appropriate Singulair® utilization, and appropriate utilization of hormone therapies. <u>Board discussion</u> Salley Page-Goertz asked what indications other than allergy/asthma Singulair® was being used for. Dr. Churchwell said that detail was not reviewed. Dr. Kennedy replied that some pediatric gastroenterologists use it for eosinophilic in conjunction sometimes with atarax and other medicines. He feels it is clinically effective but there's not literature that states that nor does he think it's been approved for that use. Dr. Churchwell that there are over 3,000 unique beneficiaries taking Singulair® but when the data is run against the criteria there are about 1,000 patients that hit out for not having an appropriate diagnosis in their medical history. Dr. Waite suggested that it could just be poor documentation. Dr. Kennedy said that he also sees where Singulair® is being inappropriately used as a first line of therapy for mild persistent to moderate persistent asthma as opposed to an inhaled steroid. Dr. Burke would have liked to have seen and age distribution but he speculated that beneficiaries may have started with asthma or reactive airway disease but now have COPD. Dr. Burke liked the hormone therapies and polypsychopharmacy topics. Ms. Dowd indicated that it the polypsychopharmacy had not been reviewed previously. Dr. Burke responded that it might be a good topic because of the large number of hits and these classes cannot be otherwise restricted. An example is combination use of antidepressants is considered appropriate therapy. Dr. Churchwell clarified that items hitting on this criteria were from multiple drug classes. Long term utilization with adjunctive therapy can sometimes be an issue and it might be useful to have prescribers take a step back and review drug regimens. Letters would be mailed for those criteria with the highest risk scores so that would be about a thousand letters for this topic. That is a good number for each topic because of the amount of work involved. Salley Page-Goertz asked if the overall goal of the program was to find an intervention to help the program in terms of cost containment or patient safety. Dr. Churchwell responded that it is both but safety is the first priority and includes prevention and provider education as well. Sometimes costs would increase because patients would be more compliant and taking medication more often. Dr. Kennedy asked if there were multiple prescribers considered in the polypsychopharmacy review. Dr. Churchwell responded that many things are reviewed with the profile: patient data (age/gender), list of alerts, medication history (prescribers/pharmacies), diagnosis history. Ms. Dowd asked if over-the-counter use was included in the NSAIDs and cardiovascular data. Dr. Churchwell replied that no, it will only be those in paid claim history. Ms. Dowd indicated that over-the-counter use is so common; the number of hits would be higher. Dr.	

	Waite suggested this become a DUR newsletter topic versus intervention topic because the audience would be broader. The board reviewed the topic intervention history and then discussed each topic. It was noted that last year three psychiatric topics. -Appropriate migraine/headache therapy - Headaches were reviewed in 2007. Dr. Burke indicated migraine/headache therapy was a clear area of misuse. Dr. Churchwell said the main issue is with butalbital products. Other products have limits already in place and do not appear to be a problem. -NSAIDs and cardiovascular disease – NSAIDS were reviewed in 2009 but not in combination with cardiovascular disease. Dr. Kennedy recommended it be included as a topic intervention. -Therapeutic duplication – this hasn't been addressed specifically although polypharmacy has been looked at before. The number of hits is relatively low although overlapping therapy is an important topic. It would be a good safety issue to be addressed. -Non-adherence to anti-hypertension regimen – Salley Page-Goertz asked if pharmacies notify beneficiaries when their anti-hypertensives need to be filled. Mr. Sutherland said software is available that can be used to contact beneficiaries to ask if they want prescriptions to be auto filled. Hypertension was a topic in both 2006 and 2008 which shows there is poor compliance with anti-hypertensives. Dr. Waite said that it's not particularly the pharmacy program that would be affected by non-compliance but the hidden cost downstream in other programs that is affected. Dr. Churchwell indicated that it would be a good tool to notify the prescribers which patients are non-compliant. -Polypsychopharmacy – The board agreed this would require a lot of work because everyone's opinion of appropriate prescribing is different. Ms. Dowd pointed out that this had the largest number of unique beneficiaries and Salley Page-Goertz indicated it has the largest cost. Dr. Churchwell indicated it would be most useful for those patients getting drugs from multiple prescribers. -Appropriate Singulair® utilization- Dr. Kennedy said it is hard to make a decision with the information provided. He recommended additional information such as age and diagnosis be considered. Dr. Waite said it's 50/50 by dosage form (pediatric vs. adult) and it was suggested the board review again next year. Asthma interventions were completed in 2007 and 2009. Matthew Stafford, Merck, provided comment that although the data was already discussed, he wanted to add that Singulair® going generic in April 2012 and the potential for cost savings may be reduced because the intervention would be after the generic product is released. -Appropriate utilization of hormone therapies – the committee agreed that clinicians are aware of appropriate therapies. Ms. Dowd recommended combining cardiometabolic effects with antipsychotics with polypsychopharmacy but Dr. Churchwell said the letters for cardiometabolic effects have	

	already been mailed. She said that about half of the patients that hit on the adverse effects of antipsychotic edit also hit on the polypsychopharmacy edit. Dr. Burke cautioned that lettering the same provider in multiple situations could make the provider community angry and defensive. The board chose the following topic interventions: -NSAIDs and cardiovascular disease -Therapeutic duplication -Non-adherence to anti-hypertension regimen The PERC Committee concurred.	
V. Public Comment	There was no public comment.	
VI. Adjourn	The meeting adjourned at 12:10 p.m. The next DUR Board meeting will be on Wednesday, January 12, 2012, beginning at 10:00 a.m. at the HP Enterprise Services Office.	Mr. Sutherland made the motion to adjourn. Dr. Waite seconded the motion. The motion passed unanimously.